AF
SFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1st named inventor:	Sheng-Ping Zhong
Application No.	09/993,907
Filed:	November 27, 2001
Title:	IMPLANTABLE OR INSERTABLE MEDICAL DEVICES VISIBLE UNDER MAGNETIC RESONANCE IMAGING
Art Unit:	3737
Examiner:	Ruth S. Smith
Confirmation No.:	7678
Docket No.:	01-286

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. §1.192

I. BRIEF ON APPEAL

As set forth in the Notice of Appeal filed by first-class mail on November 14, 2005, Appellants hereby appeal the final decision of the Examiner in the above-identified application rejecting claims 1, 3-8, 10-12, 15-38 and 69.

Appellant respectfully requests that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of the claimed subject matter.

II. REAL PARTY IN INTEREST

Scimed Life Systems, Inc. is the assignee of the present invention and the real party in interest.

III. RELATED APPEALS AND INTERFERENCES

No other appeals or interferences within the meaning of 37 CFR 1.912(c)are known to Appellants, Appellants' legal representative, or the assignees, which will directly affect, be directly affected by, or have a bearing on the Board's decision in the present appeal.

IV. STATUS OF CLAIMS

The presently pending claims are claims 1, 3-8, 10-12, 15-38 and 69. Claims 39-41, 43, 44 and 46-68 have been withdrawn from consideration pursuant to a requirement for restriction. A copy of claims 1, 3-8, 10-12, 15-38 and 69 is provided in the attached Appendix.

Claims 1, 3-5, 30 and 35 stand finally rejected under 35 U.S.C (102 b) as being anticipated by DiCosmo et al. US 6,475,516 (DiCosmo).

Claims 1, 3-7, 30 and 35 stand finally rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne US 5,331,027.

Claims 1, 3-5, 10, 11, 15-22, 28-31 and 35 stand finally rejected under 35 U.S.C. 102(b) as being anticipated by Weissleder US 5,514,379.

Claims 6-8 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Michaels US 6,112,908.

Claim 12 stands finally rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Klaveness et al. US 6,610,269 (Klaveness).

Claim 23 stands finally rejected under 35 U. S. C. 103(a) as being unpatentable over Weissleder in view of Peng et al. US 2002/0061871 (Peng).

Claims 24-27, 32 and 33 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Cleary et al. US 2003/0170308 (Cleary).

Claims 34, 36-38 and 69 stand finally rejected under 36 U.S.C. 103(a) as being unpatentable over Weissleder.

V. STATUS OF AMENDMENTS

A Final Office Action was mailed on July 14, 2005, rejecting Claims 1, 3-8, 10-12, 15-38 and 69. A Response was filed subsequent to the Final Office Action on September 14, 2005, and in an Advisory Action mailed on September 29, 2005, the Examiner indicated that the request for reconsideration was considered but did not place the application in condition for allowance. A rejection under 35 U.S.C. 112, however, was withdrawn. A Notice of Appeal was filed by first-class mail on November 14, 2005 and received by the Patent and Trademark Office on November 17, 2005. The claims have not been amended subsequent to the final rejection.

VI. SUMMARY OF INVENTION

The invention is adequately described in claim 1, the only independent claim, which reads as follows.

> 1. An implantable or insertable medical device comprising:
> (a) a substrate;
> (b) a hydrogel polymer coating at least a portion of the surface of the substrate, wherein said hydrogel polymer is adapted by cross-linking said hydrogel polymer to a degree sufficient to render said medical device visible under magnetic resonance imaging upon insertion or implantation of said medical device into a patient, and wherein visibility of detectable species associated with said hydrogel polymer to magnetic resonance imaging is modified by varying the degree of said cross-linking.

Advantages of the claimed invention relative to the prior art are as follows:

Insertable or implantable medical devices can be rendered visible under magnetic resonance imaging (MRI) by coating the devices with a cross-linked hydrogel polymer. The polymer is adapted by varying the degree of cross-linking so that it is sufficient in and of itself to render the device visible under MRI. In other words, the coating need not contain MRI labels, such as paramagnetic ions known in the prior art. Although such labels may be used to enhance visibility, they are not required.

Monitoring interventional procedures involving inserting or implanting medical devices by determining the position of those devices is provided in a simplified, cost-effective method relative to prior art methods.

VII. ISSUES

Is the subject matter of the appealed claims anticipated, i.e., described in, any of DiCosmo, Whitbourne and Weissleder?

Would the subject matter of the appealed claims have been obvious to one of ordinary skill in the relevant art at the time the invention was made?

VIII. GROUPING OF CLAIMS

Within the separate rejections, claims have not been argued separately.

IX. ARGUMENT

The following legal authorities are relied on in the following argument in the order in which they are cited:

MPEP 2131 and cases cited therein.

Richardson v. Susuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

In re Marshall, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (CCPA 1978).

Ex parte Rubin, 5 U.S.P.Q.2d 1461 (BPAI 1987).

Ex parte Levy, 17 U.S.P.Q2d 1461, 1464 (BPAI 1990).

MPEP 2112 IV.

In re Rijckaert, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993)

In re Oelrich, 666 F.2d 578, 581-82, 212 U.S.P.Q. 323, 326 (CCPA 1981)

In re Robertson, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999)

In re Baird, 16 F.3d 380, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994).

MPEP 2141.02, last paragraph.

In re Jones, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992)

In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q. 1596, 1598-99 (Fed. Cir. 1988)

MPEP 2142, second paragraph

Akso N.V. v. U.S. International Trade Commission, 808 F.2d 1471, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987)

Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 874, 228 U.S.P.Q. 90, 99 (Fed. Cir. 1985).

In re Clay, 966 F.2d 656, 23 U.S.P.Q. 2d, 1058, 1060 (Fed. Cir. 1992).

MPEP 2143.02 and the cases cited therein

In re Rinehart, 531 F.2d 1048, 189 U.S.P.Q. 143, 148 (CCPA 1976)

Ex parte Erlich, 3 U.S.P.Q.2d 1011 (BPAI 1986).

In re Newell, 13 U.S.P.Q.2d, 1248 (Fed. Cir. 1989)

In re Spormann, 150 U.S.P.Q. 449 (CCPA 1966).

Ex parte Levengood, 28 U.S.P.Q.2d 1300 (BPAI 1993).

The References:

DiCosmo

DiCosmo discloses hydrogel coated medical devices. The sole purpose of the hydrogel coating is to deliver drugs from the coated device. The hydrogel is cross-linked to provide a matrix to carry the gel. However, DiCosmo does not mention magnetic resonance imaging in any respect, much less the concept of cross-linking a hydrogel polymer to a degree sufficient to render a medical device visible under MRI.

Whitbourne

Whitbourne discloses "lubricious" coatings for medical devices that decrease the coefficient of friction of the surface of those devices. The coatings are resistant to wet abrasion. The coatings consist of a hydrophilic polymer and a hydrophobic polymer, and there may be cross-linking between the two polymers. Additional cross-linking agents may be provided, but the only functions disclosed for the cross-linking are to improve adhesion to the substrate device and improve resistance to wet abrasion. MRI is not disclosed.

Weissleder

Weissleder discloses crosslinked hydrogels, which may be loaded with therapeutic agents or "reporter" groups, i.e., labels for, various imaging techniques including MRI. The hydrogels may be injected into a patient or coated on a medical device. A paramagnetic label is required for visibility under MRI.

Michaels

Michaels discloses membrane laminate structures useful for osmotic distillation. Glycerin is taught by Michaels only as a plasticizer, not as a proton source for MRI, which is not mentioned in the reference.

Klaveness

Klaveness discloses compositions that include a vector moiety having affinity for an angiogenesis-related endothelial cell receptor, a linker moiety, which may be polymeric, and a macromolecular or particulate moiety that provides a multiplicity of labels detectable in *in vivo* imaging, e.g., MRI. Among the MRI labels disclosed are starch-coated iron oxide particles.

Peng

Peng discloses pharmaceutical compositions, in particular photochemotherapeutic agents. Chelating agents are included in the compositions for several purposes (paragraphs [0048] and [0050]). Aminopolycarboxylic acids are disclosed as known chelating agents. There is no other disclosure relevant to the appealed claims.

Cleary

Cleary discloses film forming hydrogel compositions useful in wound dressings. Among hydrophylic polymers disclosed as suitable for use in the hydrogel compositions are polymers and copolymers of acrylic acid and its derivatives.

The Rejections

A. Claims 1, 3-5, 30 and 35 over DiCosmo – Anticipation

For a reference to anticipate a claim it must disclose each an every element of the claim. See MPEP 2131 and cases cited therein. See also *Richardson v. Susuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (Fed. Cir. 1978).

Elements lacking in DiCosmo are a hydrogel polymer (a) which is cross-linked to a degree sufficient to provide MRI visibility and (b) whose MRI visibility is modified by varying the degree of cross-linking. In fact, DiCosmo does not even mention magnetic resonance

imaging at all. Rather, the DiCosmo device is used to deliver drugs from a hydrogel. Being devoid of even the *concept* of MRI imaging entirely, the reference could hardly *teach* a hydrogel polymer (a) whose MRI visibility is modified by varying the degree of cross-linking and (b) which is cross-linked to a degree sufficient to provide MRI visibility. See *Ex parte Rubin*, 5 U.S.P.Q.2d 1461 (BPAI 1987).

The examiner has asserted that the present claims would be inherent in the reference disclosure. There is, however, no evidence or clear explanation to support the examiner's assertion:

> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)....

MPEP 2112 IV.

A holding of inherency must flow as a necessary conclusion from the prior art, not simply a possible one.

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 U.S.P.Q. 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)...

MPEP 2112 IV.

The limitation "said hydrogel polymer is adapted by cross-linking said hydrogel polymer to a degree sufficient to render said medical device visible under magnetic resonance imaging" cannot be said to flow as a necessary conclusion from the prior art.

Furthermore, even assuming *arguendo* that a particular cross-linked gel within the disclosure of DiCosmo is MRI detectable, the reference would still not be an anticipation. Within product claim 1 is found a limitation that "visibility of detectable species associated with said hydrogel polymer to magnetic resonance imaging is modified by varying the degree of said cross-linking." The concept embodied by that limitation is lacking from the reference.

B. Claims 1, 3-7, 30 and 35 over Whitbourne - Anticipation

Whitbourne discloses "lubricious" coatings. As with DiCosmo, magnetic resonance imaging is not disclosed, much less so the concepts embodied by the limitations of the present claims. Moreover, there is no support for a holding of inherency, specifically, there is no evidence or clear explanation to support the conclusion that the claimed subject matter would flow as a necessary conclusion from the prior art. See the prior decisions cited above as authority.

C. Claims 1, 3-5, 10, 11, 15-22, 28-31 and 35 over Weissleder - Anticipation

With regard to Weissleder, the examiner has also argued that the cross-linked hydrogels disclosed therein would inherently be visible under MRI and that the coated medical devices disclosed would meet the limitations of the present claims. With regard to this reference as well, the examiner's conclusion is erroneous, because the two important concepts discussed above are lacking from this reference.

In Weissleder, the main purpose of cross-linking appears to be to ensure insolubility of the hydrogel disclosed. See, e.g., col. 6, lines 33-39. If the hydrogel were soluble, it could not be loaded with the *required* reporter groups or labels.

In particular, Weissleder discloses that a "reporter" group, which is a "label", is required for the cross-linked polymer to be suitable for imaging by techniques including MRI. Specific teachings follow.

At column 1, lines 39-47, in discussing the prior art in contrast to his invention, Weissleder states that the prior art drugs "are typically not detectable by conventional CT or MR imaging techniques, because they do not contain radiopaque or magnetically active labels ("contrast agents")." This apparently is to be contrasted because the compositions of his invention *do* contain active labels.

At column 4, lines 1-8, it is the reporter group, or label, e.g., a gadolinium compound, that results in MRI detection.

At column 4, lines 42-55, where the imaging techniques of the invention are summarized, it is again stated that the "labeled hydrogel" is used to provide an MR image and that the *label* is detected. See also co. 5, lines 3-19.

At column 5, lines 24-31, where coated medical devices are disclosed, it is required that a reporter group or label such as a gadolinium compound be present in the coating, as follows:

> The invention also features a method for providing an image of an interventional device in an internal region of a patient in real time by coating the device with a *labeled* hydrogel, using the device in an internal region in the patient, and scanning the patient using an imaging technique that can detect the *label* to obtain an image of the device.

(Emphasis supplied.)

Diagnostic labels are discussed and itemized at column 8, line 18, to column 9, line 22.

Consistent with the above, in all Examples in which MR testing (including T1 measurements--T1 is an indication of the time it takes hydrogen protons to return to their normal equilibrium state after excitation) is carried out (i.e., Examples 6, 7 and 8), a T1 contrast agent such as a gadolinium compound is employed.

In Example 13, a medical device coated with a paramagnetic hydrogel is disclosed. The hydrogel is loaded with a gadolinium compound to make it detectable by MRI. That is the only exemplary disclosure of an MRI detectable coated medical device.

Example 14 discloses a "Hydrogel Matrix for Cell Support." The disclosure in that example which is quite relevant to the issues here is the following.

> *If an appropriate label* is also loaded into this hydrogel, an MR image will indicate cell density and activity, and/or the presence or concentration of the therapeutic agents, in the hydrogel. (emphasis supplied)

The foregoing quotations are the most literal and positive indication that paramagnetic labels are required for MR imaging. It should also be noted that in the claims of Weissleder, it is only labeled hydrogels are claimed to be MRI imageable.

In light of the foregoing discussion, it should be clear that Weissleder actually teaches away from the basic concept of the here claimed invention, which adapts the hydrogel polymer for MRI visibility simply by cross-linking to a sufficient degree and modifies the visibility of the hydrogel by varying the degree of cross-linking. *In re Baird*, 16 F.3d 380, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994). Also see the cases cited in MPEP 2141.02, last paragraph.

Appealed claims 10-12 and 15-23 are drawn to providing further "enhanced" MRI visibility by additionally incorporating paramagnetic compounds (see specification, paragraph [0034]). However, because those claims are dependent directly or indirectly on claim 1, they include the limitations of that independent claim, that is, the cross-linking alone must be adequate for MRI visibility.

It is apparent from the foregoing discussion that the examiner's conclusion of anticipation of the appealed claims by Weissleder is clearly erroneous and should be reversed.

D. Claims 6-8 over Weissleder and Michaels – Obviousness

The "detectable protons" of claims 6-8 comprise the mechanism by which MRI functions, i.e., it is those species that are actually detected. See specification, paragraphs [0024] to [0027]. As disclosed therein, it is the cross-linking in this invention that increases the association of those detectable species with the hydrogel to make their localization adequate to provide visibility, i.e., an MR image. See also specification, paragraph [0019]. That is a fundamental distinction over the Weissleder reference, which requires paramagnetic compounds to provide an image.

The defects in Weissleder as a reference have been discussed above. Michaels discloses glycerin only as a plasticizer, and its disclosure would add nothing relevant to the disclosure of Weissleder discussed at length above, especially since no suggestion or motivation to combine the reference teachings can be found in the references. *In re Jones*, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992), *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q. 1596, 1598-99 (Fed. Cir. 1988). In the absence of any such suggestion or motivation, the combination of reference teachings can only be made with the use of undue hindsight. See MPEP 2142, second paragraph. Also see *Akso N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987). Also see, *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985).

E. Claim 12 over Weissleder and Klaveness – Obviousness

The nature of the Klaveness disclosure has been set forth above in the description of the references. Starch-coated iron oxide particles are acknowledged to be known paramagnetic particles, so Klaveness adds nothing relevant to Weissleder.

F. Claim 23 over Weissleder and Peng – Obviousness

Peng does not remedy the defects in Weissleder. As set forth in the description of Peng above, aminopolycarboxylic acids are known chelating agents. Since Peng discloses pharmaceutical compositions and not coated medical devices, the combination of references is

questionable in the first instance. *In re Clay*, 966 F.2d 656, 23 U.S.P.Q. 2d, 1058, 1060 (Fed. Cir. 1992).

Moreover, since Peng requires paramagnetic compounds for MRI visibility, it can add nothing relevant to Weissleder as applied to the appealed claims.

Furthermore, even assuming for the sake of argument that the references could be combined or modified as asserted by the examiner, they would not result in appellants' invention, and there is no support for a holding of inherency. See the prior decisions cited above for authority.

G. Claims 24-27, 32 and 33 over Weissleder and Cleary – Obviousness

Cleary discloses acrylic acid polymers and copolymers as film forming compositions useful in medical dressings. Coated medical devices are not disclosed. The examiner has not explained where the suggestion and motivation to combine these references in the manner done by the examiner could be found in the references themselves. See *In re Jones*, *supra*, and *In re Fine*, *supra*.

Furthermore one of ordinary skill in the relevant art would not have had a reasonable expectation of success for the substitution of polymers as suggested by the examiner. See MPEP 2143.02 and the cases cited therein. Of particular relevance to this case is *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143, 148 (CCPA 1976), in which it was held that inherency and obviousness are two entirely different concepts, and allegations of inherency do not substitute for a showing of reasonable expectation of success.

To a large extent this rejection, and the other rejections under 35 U.S.C. 103 discussed herein, reflect the long discredited "obvious-to-try" standard. See, merely for a recent example, *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (BPAI 1986).

Furthermore, the combination of references would not result in the here-claimed invention, because of the necessity for paramagnetic materials found in Weissleder. The present *claims do not require paramagnetic materials for MRI visibility, as discussed at length above.*

H. Claims 34, 36-38 and 69 over Weissleder – Obviousness

As discussed at great length above, Weissleder fails to anticipate claims 1, 3-5, 10, 11, 15-22, 28-31 and 35. The rejection of these claims for obviousness, as did the rejection for

anticipation, relies on an assertion of inherency supported only by unfounded speculation. That issue has been discussed at length above. The above discussed constraints on assertions of inherency apply to obviousness rejections as well as rejections for anticipation. *In re Newell*, 13 U.S.P.Q.2d, 1248 (Fed. Cir. 1989), *In re Spormann*, 150 U.S.P.Q. 449 (Fed. Cir. 1966).

In this rejection the examiner has relied also on statements of obviousness with no supporting authority. The error innate in concluding obviousness or inherency, absent support in the references and/or a clear and convincing explanation based on sound scientific reasoning, has been discussed above. See particularly *Ex parte Levy, supra.* See also see *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (BPAI 1993).

X. CONCLUSION

The references relied on by the examiner support neither anticipation nor a *prima facie* case of obviousness against any of the appealed claims. Thus, it is respectfully submitted that reversal of the rejections of record is in order.

XI. FEES

The Office is authorized to charge any fees due and owing in respect to the filing of this paper to deposit account number 50-1047.

Respectfully submitted,

David B. Bonham Reg. No. 34,297

Certificate of Mail

I hereby certify that this document is being deposited with the US Postal Service as first class mail under 37 C.F.R. 1.8 and addressed to: Mail Stop Appeal Brief – Patents; Commissioner for Patents; PO Box 1450; Alexandria, VA 22313-1450 on

1/17/06

Marjorie Scariati

(Printed Name of Person Mailing Correspondence)

(Signature)

APPENDIX

1. (Previously Presented) An implantable or insertable medical device comprising:

(a) a substrate;

(b) a hydrogel polymer coating at least a portion of the surface of the substrate, wherein said hydrogel polymer is adapted by cross-linking said hydrogel polymer to a degree sufficient to render said medical device visible under magnetic resonance imaging upon insertion or implantation of said medical device into a patient, and wherein visibility of detectable species associated with said hydrogel polymer to magnetic resonance imaging is modified by varying the degree of said cross-linking.

2. (Cancelled)

3. (Original) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is adapted by decreasing the relaxation time of said detectable species associated with said hydrogel polymer relative to the relaxation time of detectable species in the environment surrounding the device.

4. (Original) The implantable or insertable medical device of claim 3, wherein said detectable species associated with said hydrogel polymer comprise detectable protons.

5. (Original) The implantable or insertable medical device of claim 4, wherein water molecules associated with said hydrogel polymer comprise said detectable protons.

6. (Original) The implantable or insertable medical device of claim 4, wherein hydroxyl groups associated with said hydrogel polymer comprise said detectable protons.

7. (Original) The implantable or insertable medical device of claim 6, wherein a compound dispersed within said hydrogel polymer comprises said hydroxyl groups.

8. (Original) The implantable or insertable medical device of claim 7, wherein said compound dispersed with said hydrogel polymer comprises glycerin.

9. (Cancelled)

10. (Original) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is adapted by incorporating paramagnetic ions in said hydrogel polymer.

11. (Previously Presented) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is adapted by incorporating paramagnetic particles in said hydrogel polymer.

12. (Original) The implantable or insertable medical device or claim 11, wherein said paramagnetic particles comprise starch-coated iron oxide particles.

13. (Cancelled)

14. (Cancelled)

15. (Original) The implantable or insertable medical device of claim 10 wherein said hydrogel polymer comprises paramagnetic ion chelating groups.

16. (Original) The implantable or insertable medical device of claim 15, wherein said paramagnetic ion chelating groups are covalently bonded to the hydrogel polymer.

17. (Original) The implantable or insertable medical device of claim 10, wherein said hydrogel polymer comprises a paramagnetic ion chelation complex.

18. (Original) The implantable or insertable medical device of claim 17, wherein said paramagnetic ion chelation complex is covalently bonded to said hydrogel polymer.

19. (Original) The implantable or insertable medical device of claim 10, wherein said paramagnetic ions are selected from the group of chromium (III), manganese (II), iron (III), iron (II), cobalt (II), copper (II), nickel (II), praesodymium (III), neodymium (III), samarium (III), ytterbium (III), gadolinium (III), terbium (III), dysprosium (III), holmium (III) and erbium (III).

20. (Original) The implantable or insertable medical device of claim 19 wherein said paramagnetic ions comprise gadolinium (III).

21. (Original) The implantable or insertable medical device of claim 15, wherein said paramagnetic ion chelating groups comprise organic acid functional groups.

22. (Original) The implantable or insertable medical device of claim 15, wherein said paramagnetic ion chelating groups comprise carboxyl groups.

23. (Original) The implantable or insertable medical device of claim 15, wherein said paramagnetic ion chelating groups comprise aminopolycarboxylic acid groups.

24. (Original) The implantable or insertable medical device of claim 22, wherein said hydrogel polymer comprises substituted or unsubstituted acrylic acid monomer units.

25. (Original) The implantable or insertable medical device of claim 24, wherein said hydrogel polymer comprises polyacrylic acid.

26. (Original) The implantable or insertable medical device of claim 24, wherein said hydrogel polymer further comprises substituted or unsubstituted acrylamide monomer units.

27. (Original) The implantable or insertable medical device of claim 26, wherein said hydrogel polymer is a copolymer of acrylic acid and acrylamide.

28. (Original) The implantable or insertable medical device of claim 17, wherein said paramagnetic ion chelation complex is selected from the group consisting of diethylene triamine

pentaacetic acid (DTPA), tetraazacyclododecane tetraacetic acid (DOTA), and tetraazacyclo tetradecane tetraacetic acid (TETA).

29. (Original) The implantable or insertable medical device of claim 28, wherein said paramagnetic chelation complex comprises diethylenetriamine pentaacetic acid (DTPA).

30. (Original) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is selected from the group consisting of polyacrylates; poly(acrylic acid); poly(methacrylic acid); polyacrylamides; poly(N-alkylacrylamides); polyalkylene oxides; poly(ethylene oxide); poly(propylene) oxide; poly(vinyl alcohol); polyvinyl aromatics; poly(vinylpyrrolidone); poly(ethyleneimine); polyethylene amine; polyacrylonitrile; polyvinyl sulfonic acid; polyamides; poly(L-lysine); hydrophilic polyurethanes; maleic anhydride polymers; proteins; collagen; cellulosic polymers; methyl cellulose; carboxymethyl cellulose; dextran; carboxymethyl dextran; modified dextran; alginates; alginic acid; pectinic acid; hyaluronic acid; chitin; pullulan; gelatin; gellan; xanthan; carboxymethyl starch; chondroitin sulfate; guar; starch; and copolymers, mixtures and derivatives thereof.

31. (Original) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is selected from the group consisting of poly(acrylic acid); polyacrylamide; poly(N-alkylacrylamide); copolymers of acrylic acid and acrylamide; poly(ethylene oxide); poly(propylene oxide); copolymers of ethylene oxide and propylene oxide; hyaluronic acid; and poly(L-lysine).

32. (Original) The implantable or insertable medical device of claim 31, wherein said hydrogel polymer comprises poly(acrylic acid).

33. (Original) The implantable or insertable medical device of claim 31, wherein said hydrogel polymer comprises a copolymer of acrylic acid and acrylamide.

34. (Original) The implantable or insertable medical device of claim 1, further comprising a lubricious coating layer disposed on said hydrogel polymer.

35. (Original) The implantable or insertable medical device of claim 1, wherein said medical device is selected from the group consisting of catheters, guide wires, balloons and stents.

36. (Original) The implantable or insertable medical device of claim 35, wherein said catheter is a neuro-interventional microcatheter.

37. (Original) The implantable or insertable medical device of claim 35, wherein the stent is selected from the group consisting of endovascular, biliary, tracheal, gastrointestinal, urethral, ureteral and esophageal stents.

38. (Original) The implantable or insertable medical device of claim 37, wherein the stent is a coronary stent.

69. (Previously Presented) The implantable or insertable medical device of claim 1 wherein a primer coating to enhance adherence of said hydrogel polymer (b) to said substrate (a) is applied to said substrate prior to coating with said hydrogel polymer.